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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,817	04/09/2004	Robert K. Schultz	2801-0187P	8899
2292	7590	02/17/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/820,817	Applicant(s) SCHULTZ ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt of Applicant's amendments and remarks, filed 12/7/2005, is acknowledged. Claims 11 – 20 were cancelled. Claims 1 – 10 are pending in this action.

It is recognized that Applicant submitted several non-patent references with the reply filed 12/7/2005. However, Applicant did not submit an information disclosure statement accompanying those references. It is not clear if these references were already listed on a previously submitted information disclosure statement. However, Examiner has considered the references submitted by applicant.

Response to Arguments

Applicant's arguments with regard to the rejection of claims 1 – 10 under 35 USC 103(a) is persuasive in light of the amendment. Accordingly, these rejections are withdrawn.

However, the new grounds of rejection discussed below are deemed necessary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 5, 12, and 13 of U.S. Patent No. 6,743,413 in view of Greenleaf, US 5,427,282. Although the conflicting claims are not identical, they are not patentably distinct from each other because while instant claims are drawn to a method of preparing a metered dose inhaler, patented claims are drawn to a metered dose inhaler. The contents of the metered dose inhaler of patented claims are identical to that of the formulation to be added to the metered dose inhaler of instant claims. Patented claims do not recite a metered dose inhaler having a metering valve that has a valve seal comprising surfactant.

Greenleaf teaches a metered dose inhaler having a metering valve that has a valve seal comprising surfactant, and further teaches that this is an advantageous valve, since it shows enhanced the force-to-fire and improved return force compared to valves without surfactant.

As such, the artisan would be motivated to use this type of metered dose inhaler according to the teachings of Greenleaf. A person of skill in the art would find it obvious to add the formulation to the valve in any order, or to prepare the mixture inside the inhaler before adding or to add the components separately to the inhaler, as these are

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manipulations that can be practiced according to the convenience of the artisan, who would enjoy a reasonable expectation of success at doing so.

Claims 1 – 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 18 of U.S. Patent No. 5,427,282 in view of US 6,743,413, to Schultz et al.

Greenleaf claims a metered dose inhaler having a metering valve that has a valve seal comprising surfactant, and further teaches that this is an advantageous valve, since it shows enhanced the force-to-fire and improved return force compared to valves without surfactant. Greenleaf also claims a method of preparing a metered dose inhaler comprising such a valve.

Greenleaf does not teach a method of preparing a metered dose inhaler by adding a formulation, as specified in instant claims, thereto.

Schultz teaches the formulation of instant claims for use in aerosols, specifically in metered dose inhalers (abstract, col. 6, lines 21 – 51, claims 1 – 5, 12, 13). Schultz further motivates the use of this formulation, by teaching that the formulation allows for reproducible dosing without flocculating (col. 2, lines 33 – 42).

Accordingly, the artisan would find it obvious to prepare a metered dose inhaler according to Greenleaf by using the formulation according to Schultz. The motivation to do so comes from Schultz, who teaches specific advantages in using the formulation of Schultz. The artisan would find it obvious to add the formulation to the metered dose inhaler in order to prepare it. With respect to the order of addition of the ingredients, and the formulation being prepared either in the inhaler or prepared first and then added

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to the inhaler, the artisan would see these variables to be a matter of convenience, and, lacking an unexpected result, would be motivated to make such manipulations to allow for the best manufacturing process. Since these are simple manipulations in the art, the artisan would have a reasonable expectation of success.

Conclusion

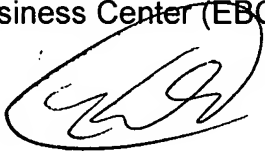
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric E. Silverman, PhD
Art Unit 1615



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